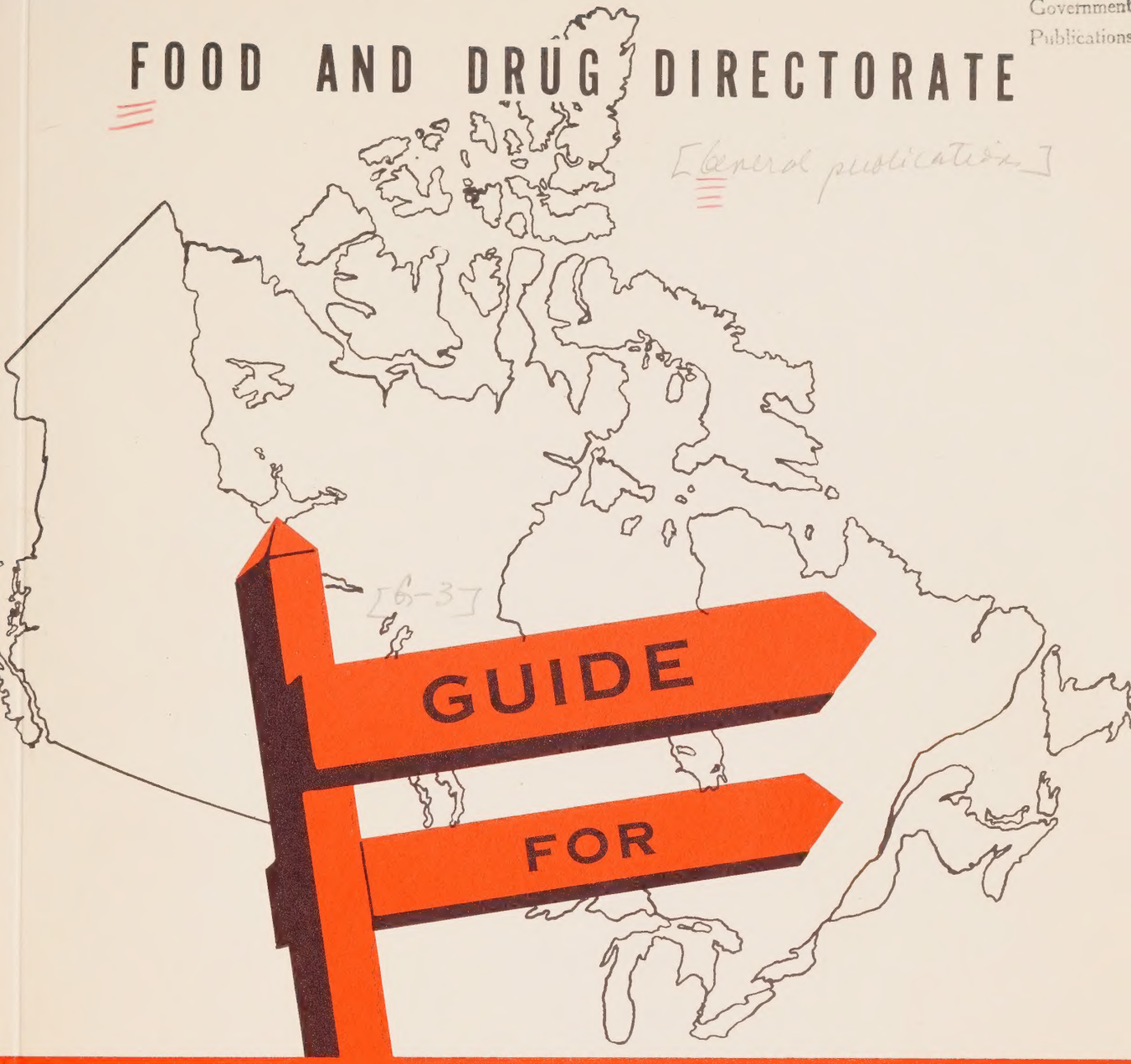
FOOD AND DRUG DIRECTORATE



MANUFACTURERS AND ADVERTISERS

DEPARTMENT OF NATIONAL HEALTH AND WELFARE – OTTAWA, CANADA

GUIDE FOR MANUFACTURERS AND ADVERTISERS

Produced by

Inspection and Enforcement Services

Food and Drug Directorate

Department of National Health and Welfare

by authority of

The Honourable

The Minister of

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PREFACE

Advertising, labelling and packaging are important procedures in marketing any product and no commodity receives more attention in this respect than foods, drugs, cosmetics and devices.

While advertising and displaying goods in an attractive manner is essential to the merchant in this competitive world, it is also useful and helpful to the consumer if fairly and honestly done. On the other hand it may be abused in such a way as to cheat and deceive the consumer through the employment of unfair and dishonest practices. Such objectionable methods are a disadvantage to ethical competitors and a serious harm to trade as a whole.

General principles of honest and fair practices are presented in the Fair Trade Code for Advertising and Selling of the Association of Canadian Better Business Bureaux, Inc. The interpretation of the specific requirements of the Food and Drugs Act and Regulations set forth in the following pages adheres to these principles. The following principles are quoted from this code,-

I

Serve the public with honest values.

II

Tell the truth about what is offered.

III

Tell the truth in a forthright manner so its significance may be understood by the trusting as well as the analytical.

IV

Tell customers what they want to know – what they have a right to know about what is offered so that they may buy wisely and obtain the maximum satisfaction from their purchases.

V

Be prepared and willing to make good as promised and without quibble on any guarantee offered.

VI

Be sure that the normal use of merchandise or services offered will not be hazardous to public health or life.

GUIDE FOR MANUFACTURERS AND ADVERTISERS

A. INTRODUCTION

A. 1. **Reason for Guide.** The Department has often been asked for its point of view in interpreting and administering the Food and Drugs Act and the Food and Drug Regulations where advertising and labelling are concerned.

Neither the Act nor the Regulations attempt to specify in detail in all cases what may or may not be done under the law. While the Regulations in some cases do supply exact instructions the Act contents itself in most cases with expressing intent. For example, for foods, drugs, and devices, the Act states that no person shall label, package, treat, process, sell or advertise any food, drug, or device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety, but it does not say what is a false claim, or a misleading or deceptive one, and the administering officers are expected to determine this on the basis of opinion. Through the years a considerable store of opinion has accumulated resting in some cases upon court decisions and in others upon general acceptance of its fairness, common sense, and need. It only remains to be said that opinions of officials are not the law and that the final decision resides with the courts of the land.

This GUIDE cannot be comprehensive, and it is not intended to cover every conceivable case, but it will attempt to deal with some of the more common or the less understood features of administrative control. While it is unlikely that there will be many, frequent, or petty changes, this GUIDE must not be regarded as a static document. It will be supplemented or amended from time to time as occasion arises and will also reflect the changing pattern of the legislation.

Finally it is believed that acceptance of the GUIDE will go far to promote uniformity over the field it covers and to depress unfair practices.

A. 2. **Authority for Control.** The authority under which the Department regulates labelling and advertising stems from

(a) the Act creating the Department,

(b) the Food and Drugs Act,

(c) the Food and Drug Regulations,

(d) the Proprietary or Patent Medicine Act,

and full weight is given to the pertinent sections. In addition, Regulation 10 of the Radio Station Broadcasting Regulations, Regulation 11 of the Radio (TV) Broadcasting Regulations and Extracts from the Broadcasting Act, 1958 require that no continuity of the type described in those sections may be broadcast until it has been approved by the Department of National Health and Welfare.

A. 3. **Intent of Control.** It is universally accepted that procedures under the legislative powers to protect against injury to health will be prompt and definite. It is not always realized that the Food and Drugs Act is not only a health measure but also is designed to afford protection to the consumer of foods, drugs, cosmetics, or therapeutic devices against fraud. The administrative endeavour is made to afford the most exemplary measure of protection in those fields in which the consumer cannot reasonably be expected to acquire expert knowledge. Claims referring to flavour, appearance, texture, culinary advantages and such others where normally the consumer is well able to follow his own judgment or preference are usually not critically reviewed; on the other hand technical, scientific, quasi-scientific, therapeutic, medical, nutritional, and educational expositions must of necessity be considered from the appropriate viewpoint.

A. 4. **Food, Drug, Cosmetic, or Device.** Each of these is considered as a separate entity and each product is classed according to claims made for it.

A. 5. **Labels as Advertisements.** The Act defines what is meant by a label and by an advertisement but these terms are not mutually exclusive. Labels must have certain information as demanded by the Act or Regulations, but information or claims in excess of those which are mandatory may be deemed to be advertising. Package inserts may in certain circumstances be part of the labelling while still being advertising. Advertising may purport to reproduce facsimiles of labels and the labels then become wholly advertisements.

A. 6. **Labelling.** The Regulations are now so constructed that it is relatively easy to discover what is mandatory information for a label for any commodity.

The main panel is usually the area on which the brand name and the common name appear in English or French. However, a small panel, or the smallest panel cannot become the main panel by virtue of having the name of the article appear thereon and nowhere else. For bottles, cartons, cans and similar containers, the face which is usually displayed to the public on the shelves is considered to be the main panel. For flat containers, the top part is the main panel.

The width of the main panel should not exceed ⅓ the circumference of cylindrical containers. However, when the brand name or common name is lengthy their extremities may extend up to 40 per cent of the circumference. In such cases, as far as foods are concerned, the net contents should appear within the ⅓ area calculated from the centre of the main panel.

Another expression that is used in connection with drugs and cosmetics is "both the inner and the outer labels". Usually a product has only one label. This single label then becomes both the inner and the outer label and as such must carry the information required to appear on both labels. However, shipping wrappers are not usually considered to be the outer label.

Inner label, and outer label, are defined in the Regulations. Where a sales package has more than two sets of labels, i.e. more than one outer label, any intermediate label will be deemed to be an outer label if the package is further subdivided for sale so as to render such intermediate label an outer label. A sanitary lining or wrapper, where used, will not be regarded as an inner label unless it constitutes the sole wrapping.

Shipments of a single commodity in bulk should normally be completely labelled though at times this may not be practicable. Way bills or invoices identifying the goods may in certain cases carry some of the required information, particularly in the case of imports intended for manufacturing or subsequent packaging.

A. 7. **Amendments to Act and Regulations.** Any amendment to the Act must be approved by Parliament and involves a lengthy process. Regulations, however, are made by Order in Council and become effective when published in the Canada Gazette Part II. They may be amended to meet new or changed conditions. Regulations so published have the force of law. Normally, consultations with organized bodies of the industries that might be affected, as distinct from individual firms, are the precursors of final action to amend the Regulations.

A. 8. **Caveat Emptor.** The conception of "let the buyer beware" is discarded, and no longer operates in the food and drug field.

A. 9. **Other Relevant Controls.** There are various kinds of special legislation in the food and drug field, for example, Acts that control production, grading, marketing, Pharmacy Acts and so forth. Usually none of these relieve foods, drugs, cosmetics or devices from the requirements of the Food and Drugs Act.

Attention is also drawn to Section 306 of the Criminal Code of Canada which deals with false advertisements. The part of this Section of the Criminal Code related to advertising that could be applicable to foods, drugs, cosmetics or medical devices is as follows:

306(2) Every one who publishes or causes to be published in an advertisement a statement or guarantee of the performance, efficacy or length of life of anything that is not based upon an adequate and proper test of that thing, the proof of which lies upon the accused, is, if the advertisement is published to promote, directly or indirectly, the sale or disposal of that thing, guilty of an offence punishable on summary conviction.

A. 10. **Approval by Department.** There is no power conferred by the Act for the Food and Drug Directorate or the Department to give approval of a label or an advertisement. The administration, within the limits of available facilities, is usually able to give an opinion as to whether a label conforms with requirements. In certain circumstances advice will also be given as to how a label may be modified satisfactorily but advice should not be expected upon how to circumvent the intent of the legislation. Opinions may also be sought upon the basic principles of proposed advertising but there are not sufficient facilities to extend this service to continuous pre-reviews.

If labels and advertising material are submitted for review they should first be drawn up by the manufacturers according to requirements before an opinion will be given as to whether the material satisfies the requirements of the Food and Drugs Act and Regulations. All submissions should be in quadruplicate unless otherwise specified.

B. 1. **Labels; Mandatory Statements.** See C. 1 for Foods and D. 1 for Drugs.

B. 2. **Labels; Names.** The name given to an article of food or drug should not lead to deception or misdirection. Names that are not in accordance with the composition or that suggest, either directly or by phonetic rendering, results that are not likely to be obtained may be improper. The fact that the name is trade-marked or is also the name of a duly incorporated company gives no protection to it under the Act. The use of the word doctor or any contraction, or any phonetic rendering of either in the name of a food or a drug is objectionable, but products that used these devices before 1927 will not be interfered with if the composition of the article has not been changed and if the article was in fact put out by a doctor of medicine, dentistry, or veterinary medicine. This applies equally to other professional titles such as nurse, professor, reverend, and the like.

A product must not use the name of another product of which it is an imitation or substitute, or which it resembles in a manner likely to deceive unless the labelling and advertising for it makes the situation quite clear. The name must not improperly suggest a place of origin. When a name or description of a product includes the name of a food the named food must be normally present in predominant or fully significant proportion. This principle can become operative even where a misleading name has been in use for a long time.

B. 3. **Common Name; Proper Name.** To prevent deception it is a general principle that foods be given their common names, and that a list of the ingredients be declared also by common names. Those foods with proprietary, brand or coined names must show on the label the common name as well if they are single foods, or standardized foods; for non-standard formulated foods the label, not necessarily the main panel, must, unless specifically exempted by the Regulations, give a complete list of the ingredients either in descending order of proportionate content or in terms of percentage or proportionate composition.

In the case of drugs, the main panel of the label of all single ingredient preparations must carry the proper name or, if there is no proper name, the common name of the drug. Proper names are defined in the Regulations. Where no proper name exists, the common name, that is the name by which the drug is commonly know, must be used.

B. 4. **Name and Address.** The Act requires that names and addresses used on label or package be not fictitious, or non-existent, and this applies to all parts of the name and address. An impressive list of offices must also be a true list. The Regulations require that the label of a package bear the name and address of the manufacturer. However, the definition of a manufacturer is quite broad and includes packers, distributors, etc., and in fact he who puts his name on the label becomes the manufacturer and must take the responsibility for the goods sold under his name.

The same holds true for foods, drugs and cosmetics except for drugs manufactured under licence. Licensed drugs, except antibiotics, are required to bear the licensed manufacturer's name and address, but the distributor may add his name, if he so wishes.

The address should be complete and the following rules should be applied:

(i) for Canada, it should include the name of the city and the province or the country.

(ii) for all other countries, the name of the city and the country.

Mail addressed to the address given on the label should reach the manufacturer.

B. 5. **Statutory Terms.** If a term, made use of in referring to a food or drug, has a meaning under any statute of the Parliament of Canada such use must conform with that meaning.

B. 6. **Reference to Food and Drugs Act and Regulations.** No general or specific reference, direct or indirect, may be made to the Act or Regulations by label or advertisement for a food, drug, cosmetic or device unless such reference is a specific requirement of the Act or Regulations.

B. 7. **Failure to disclose; Erroneous Impression.** The Act deems it to be an offence in advertisements to deal in partial truths, or to use true statements in such a way as to be liable to create an erroneous impression, and this extends to failure to disclose essential facts concerning the actual properties of the article advertised. In this connection it is usually considered to be impracticable to attempt to correct or modify a false, exaggerated, or misleading statement made in one place by an explanation made elsewhere in the advertisement or on the label. Impressions are given by other things than the actual words used so it is important to consider the effect of illustrations, of scientific, laboratory, medical, hospital surroundings, when introduced; of atmosphere, machinery, size of display, relative size of modifying statements and all other features that may enter into the make-up. The actual words used in an advertisement may be satisfactory but the total inference or implication may be entirely false or misleading.

B. 8. **Foods, Drugs, Cosmetics, or Devices Recommended as Treatments for Certain Diseases.** To advertise or sell to the general public any food, drug, cosmetic or device as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states listed in Schedule A to the Act, is regarded as a serious offence because of possible injury to health and/or fraud. The importation, advertisement, or sale of such items so represented to the general public is therefore prohibited.

Schedule A to the Act includes such conditions as Alcoholism, Cancer, Diabetes, Heart Diseases, High Blood Pressure, Influenza, Obesity, Tuberculosis and many others which, according to expert opinion, cannot be diagnosed by the individual nor can the individual treat himself adequately or safely for these conditions.

B. 9. **Obesity; Reducing Plans.** Foods, drugs, cosmetics or devices may not be imported, advertised, or sold to the general public as treatments, preventatives, or cures for Obesity.

However, the Department recognizes the fact that there is a difference between the disease condition of obesity caused by glandular malfunction and simple overweight due to overeating. The sale of reducing plans which would not contravene the provisions of the Act is permitted for overweight conditions, under the following terms:

(i) Reducing plans, programs, diets or courses which will provide a suitable reducing diet may be distributed. In all cases it is understood that it is the diet or lessened intake of calories that will be the instrument of weight reduction.

(ii) Various products may be offered as part of the reducing plan, but no claims may be made that they, in themselves, will take off weight. They should be of some use in the plan, such as help curb hunger, provide extra vitamins and minerals, provide massage and exercise, etc.

(iii) Any specific claims for these products, such as hunger control, must be substantiated by adequate data.

B. 10. **Dietary Standards.** Various official or quasi-official bodies have issued so-called dietary standards listing suggested standards for specific nutrients. Little, if any, use can be made of these in advertising individual foods or drugs as they were not constituted for such a purpose.

B. 11. **Nutrition Rules.** Nutrition rules are excellent as a guide to the public in adopting proper eating habits as regards to the diet as a whole. Little, if any, use can be made of these in advertising individual foods or drugs as they were not constituted for such a purpose. A variety of foods must be consumed in order to follow these nutrition rules.

B. 12. **Vitamins.** Part D of the Regulations is devoted to vitamins exclusively. There is in every case, whether the article be a food or a drug, a specified method of declaring the actual content of such vitamins as are present in a quantity sufficient to allow of reference to them, and this permits the consumer to rate one product against another upon a common basis. There are also imposed, except for such vitamins as occur naturally in foods, upper limits of vitamin content. From these facts it will be apparent that such words as "Rich in vitamins", "High in Potency" and the like are out of place and only serve to confuse the intent of the clear statement of content that the Regulations demand. The boundaries of the claims permissible for each vitamin are laid down in somewhat technical language, and these boundaries may not be crossed. It is however not necessary to use the quasi-technical wording of the Regulations, the only precaution to observe being that the meaning is not distorted except where statements appear in quotation marks in which case they shall be reproduced exactly.

Foods, to which no vitamins have been added, but which contribute in a reasonable daily intake, as ordinarily consumed or prepared as directed on the label, not less of a vitamin than specified in the Regulations may be advertised, depending on which of the two limits of vitamin contents is met by the food, either as "an excellent dietary source of (naming the vitamin)", or as "A good dietary source of (naming the vitamin)". No specific claims may be made for foods which can only be described as "a good dietary source of vitamin".

The label of a food to which a vitamin has been added in accordance with the requirements of the Regulations may carry the statement that the vitamin has been added or increased, whichever is appropriate. In addition, the specific claims provided in the Food and Drug Regulations for the action of the vitamin may be made if the amount added is sufficient to allow such reference.

Vitamins consumed as food cannot be depended upon to overcome gross deficiencies. All vitamins are essential, not just the one or more in the product being advertised. To advertise that an article provides vitamins is insufficient unless it provides all the vitamins, otherwise the vitamins provided should be specified. The reasonable daily intake about which the Regulations speak is usually construed as the total of the average portions consumed, without straining a point, in a day and is not based upon any requirement of continuous daily use.

No vitamins may be added to a standardized food product, unless the standard specifically permits such addition.

For drugs the smallest recommended daily intake of a preparation is the criterion by which permissibility of mention of a vitamin will be judged. On the other hand the largest recommended dose is used to determine whether the label must state "NOTE: For Therapeutic Use Only", when advertisement to the general public must cease, thus preventing the promotion of very potent preparations which the public would be inclined to buy, but which they do not require.

No manufacturer, or advertiser, is in a position to state that any adult, child, or group of people needs a particular vitamin or assemblage of vitamins and it has repeatedly been pointed out that dietary standards, and the results of dietary surveys as related to dietary standards, are entirely unsafe to use as promotional material. There is no absolute virtue in combinations of selected vitamins with other selected nutrients so arranged that they are ingested together.

Claims for food supplements are sometimes based on the depletion of nutrients in our soils, the use of chemical fertilizers, the loss in cooking and the supposed resultant lack of vitamins (and minerals) in the foods.

Scientifically controlled experiments in which treated fields were compared with unfertilized fields showed that the composition of the crop was little affected, and records of animals fed rations from these fields showed no difference in yield, breeding, efficiency or health. It might be true that

some elements are lost in cooking, but there is no evidence that abnormal physiological conditions due to a deficiency of vitamins (and minerals) exist among Canadians. It is a well known fact that the varied food consumed in the ordinary diet in this country supplies an adequate amount of nutrients. Therefore, claims of this nature will be reviewed critically.

B. 13. **Minerals.** Claims for mineral content should be reserved for those products making a significant contribution of a mineral to the diet and are to be governed by Section 5(1) of the Act in the case of food, and by Section 9(1) of the Act and C.01.004(b)(v) of the Regulations for drugs. It would not only be inappropriate, but in violation of the Act, to name or list substances or ingredients which are present in either trace amounts without any significance or in respect of which there is no known nutritional significance or medicinal function. Such listing is considered as likely to create an erroneous impression regarding the character, value, quantity, composition, or merit of the product.

In so far as food supplements are concerned, the minerals have been divided for the purpose of the Act into three classes:

(i) Minerals required in human nutrition and for which claims may be made. These are: Calcium, Iron and Phosphorus.

(ii) Minerals which may be required in human nutrition but which are usually present and for which there is no need to supplement the normal diet. They may be listed on the label but no claims should be made for them. These are: Chlorine, Cobalt, Copper, Fluorine, Iodine, Magnesium, Manganese, Molybdenum, Potassium, Sodium and Zinc.

(iii) All other minerals which have no known function in human nutrition should not be listed on the label.

Claims for Calcium and Phosphorus should be limited to helping build and maintain normal teeth and bones. Those for iron should be limited to helping in the formation of haemoglobin (red blood corpuscles) and should not give the impression that Iron alone is sufficient for blood building, or that strength, energy, vitality, endurance or the like will necessarily follow an increased iron intake. In general, claims for the actions of these three minerals will be considered as to their propriety in the light of available authoritative knowledge. If mineral analysis is published for a food or a drug, the product should always conform thereto. There is no advantage in supplying minerals in organic combinations, in fact the inorganic salt may be best. Therefore, expressions such as "Food Iodine", "Organic Iron" becomes misleading and should not be used.

B. 14. **Proteins.** Most foods contain some proteins. Their biological value depends on quality and quantity in a particular food and the total daily intake. It is quite possible that a food may contain as much as 85 per cent protein, but if the protein is not of good quality, it will be of little value to the body. Likewise, high quality proteins, if present in only minor or minute amounts, are of little value in meeting protein requirements. To prevent undue emphasis of the protein content of certain foods, the Directorate has established

a criterion based on the three above mentioned factors which regulates the protein claims which can be made for certain foods. Based on the established criterion, foods are divided into four groups, which can be described as "An excellent dietary source of protein", "High quality proteins", "Good dietary sources of protein", and those for which no claims can be made. (The claim "High in Protein" is considered misleading). Claims for the action of protein should be limited to the following: (1) Proteins help children grow; (2) Proteins are needed for the renewal and maintenance of the body tissues.

These claims should only be made for products which are excellent or good dietary sources of proteins. It is misleading to claim that proteins produce muscles or strong muscles, sturdiness, or the like.

Since a criterion has been established for protein claims, there is no need for mention of Amino Acids. To establish if the label of a manufactured food product containing protein may carry the above claims it is necessary for the manufacturer to determine the "protein rating" described by the official method which is available upon request from this Directorate.

These criteria are also considered to be applicable to protein tablets and powders sold as dietary supplements.

B. 15. **Minimum Requirements.** No minimum daily requirements for vitamins and minerals have been set in Canada as it is felt that there is such a difference in the requirements of individuals that no general statement of requirements may be made. No claim may be made for a vitamin unless there is a prescribed minimum quantity of that vitamin provided by the food or drug, and the relative value of its contribution is given in the terms specified in Part D of the Regulations. For minerals there is as yet no specific regulations but the questions as to whether a significant contribution is made by any food or drug is determined in relation to data for Canada published by recognized bodies of authority and open to all to study. The provision, for regular use, of amounts of nutrients in excess of average requirements, whether by a food or a drug, is regarded as an economic waste. Without individual examination it is not possible to state what any person's requirements are for any nutrient.

B. 16. **Iron; Anemia.** Drug preparations may not be represented as useful in the treatment of anemia in general. The most common form of anemia is due to iron deficiency and is characterized by a lowering of haemoglobin with an occasional reduction in the number of red blood cells. A drug preparation that contains a therapeutic daily dose of a suitable iron salt may be claimed to help "improve the blood", "improve the haemoglobin content of the blood", "increase the number of red blood cells", or "relieve the symptoms of iron deficiency", in the case of simple anemia. As far as secondary anemia is concerned, claims may be permitted for fatigue, lack of appetite, and nervousness.

When minute amounts of iron are present the claims should be restricted to improving the appetite and to acting as a mild tonic in convalescence and rundown conditions.

B. 17. **Minor or Trace Ingredients.** Stressing of minor or trace ingredients so as to exaggerate their importance is objectionable.

B. 18. **Stressing Particular Ingredients.** It is misleading to stress a minor ingredient present in an insignificant amount because it is of current popular appeal or for other reasons. When a list of ingredients is required for a food, the ingredients must be listed in descending order of amount present or in terms of percentage or proportionate composition.

B. 19. **Fortification; Enrichment.** "Fortification", "Enrichment" and similar terms are exceedingly difficult to employ without creating an erroneous impression, particularly where the actual operation carried out is merely an addition or an increase; "added" or "increased" would be correct words to use. Where a manufacturer makes a product and has thus complete choice of the ingredients and their proportions there can be no effect of enrichment or fortification through a variation of materials or quantities used.

B. 20. **Scientific or Technical References.** Statistics or references culled from technical literature are frequently unsuitable for commercial purposes. Physiological, nutritional, chemical or physical properties, if referred to, should be expressed in non-technical terms without false implications or improper references, particularly as to comparisons between products. In a controversial subject or where there are differences of scientific opinion it would be considered misleading to choose only favourable references with no indication that equally competent authority was not in agreement.

B. 21. **Scientific or Technical Terms.** It is not to be expected that such terms will be properly understood by the general public, and they should therefore be avoided where possible in advertising addressed to the general public. Coined technical terms should not be invented to impress the potential purchaser,

B. 22. **Analyses; Analytical Charts.** Statements purporting to be analyses are of necessity scientific in nature, rarely convey the proper meaning to the public, and do not substitute for the list of ingredients by their ordinary names when such is required by the law. Chemical analyses of foods should be used with great care, in order that the ordinary user may not be misled. To those who are on a special diet appropriate analytical data are helpful. It is particularly objectionable to stress by analytical tables the presence of elements of no real significance. Since products, except where standardized, may have an inherent variance of composition analytical figures should not be given to an accuracy greater than the variance will allow, and in fact this may lead to charges of violation if an official analysis shows a variation from the analysis as published. So-called trace-elements are of no significance in foods because, today at least, it is difficult to avoid obtaining adequate amounts of them or else their functions have not been definitely established.

B. 23. **Certificate of Analysis; Certified; Approved.** The descriptives "Certified", "Approved", and Certificates of Analysis, or the like can be misleading.

The "Canada Approved" seal of the Meat Inspection of the Department of Agriculture under the Meat and Canned Foods Act typifies an acceptable use, for it means that the meat ingredient is rigidly, and always, inspected.

B. 24. **Seals or Certificates of Approval.** Unless it is explained just what a seal or certificate of approval means its use may convey an erroneous impression of approval of every batch or unit by the approving organization. It is no substitute for technical control at the point of manufacture.

B. 25. **Doctors; Use of Professional Titles.** Doctors, scientists, nurses, professional persons in general, do not in their professional capacities, nor do hospitals ethically recommend or endorse particular brands of foods or drugs for prescription en masse. Because a person in his professional capacity has claimed success with a particular formula of a food or a drug it does not follow that the same formula will also achieve success when self-administered by the general public, for the factors of the physician's diagnosis, his personal observation of the progress of the treatment, and his variation of the treatment to suit observed conditions are wholly or essentially lacking. It is not to be accepted that a small number of supporting professional opinions must outweigh the general body of opinion in the profession, even if the non-supporters have not used or tried the product that is the subject of the opinions.

The reference to professional people is therefore considered to be misleading.

B. 26. **Testimonials, Endorsement, Prominent Persons.** Testimonials and reports of individual cases constitute a selection. There seems to be no acceptable way of indicating what relation these bear to failure or relative failures in treatment or results, so that even where the diagnosis may have been correct, the public is likely to be misled.

Testimonials are critically reviewed by the Directorate; if used, it must be remembered that any statement made is the responsibility of the advertiser and must not be in violation of the Act or Regulations. The public has no way of evaluating the status of the endorser in relation to the particular circumstances. While prominent persons may be reported as endorsing a particular thing equally prominent persons could be produced who would not endorse it.

B. 27. **The Lay Press.** It is very objectionable to quote unrestricted "write-ups" in the lay press especially if they contain statements to which exception would be taken if directly attached to the article being sold.

B. 28. **Technical, Scientific Claims.** The general public is not in a position to assess technical, scientific claims. In considering such claims the administrative review must necessarily be carried out in the light of the most authoritative scientific information available.

B. 29. **Accepted Opinion.** Isolated opinion and alleged new discoveries, even though advanced by reputable workers, are not suitable for commercial exploitation at least until they have reached the status of general acceptance, in particular because they cannot be said to have been the subject of adequate and proper trial. Science and industry are not static and the accepted opinion of yesterday may have been so revised as no longer to be suitable for commercial use today. Preparations awaiting the outcome of experiment, trials, and the like to settle whether particular claims are justifiable should not be offered to the public on the basis of, or as including, such particular claims.

B. 30. **Clinical Tests.** It is the responsibility of the seller to perform such adequate and proper tests as will protect him if he is challenged as to the validity of claims he makes when such claims are not generally accepted. In nutritional and therapeutic fields controlled clinical tests may be the only acceptable criteria. He should therefore familiarize himself with the meaning of a controlled clinical test for, in general, mere case reports or testimonials are of little or no use.

B. 31. **Educational Advertising.** Educational advertising designed to demonstrate the necessity or desirability of a food or drug should not be one-sided; it should be fair, attain proper perspective and not create apprehension.

B. 32. **Self-Diagnosis by Symptoms.** Correct diagnosis of disease or of nutritional deficiencies is exceedingly difficult even in the hands of those who have made it their special task and who are assisted by the most modern diagnostic aids and who actually examine the patient. Thus the recital of vague, general lists of common symptoms to induce the public to diagnose their condition as one which will be alleviated by a particular food or drug offered for sale is basically unsound and is likely to be objected to even if it is claimed that the preparation so offered may help in the context. It has to be remembered that the condition of perfect health is a relative, individual conception and is also related to such a large number of physiological, nutritional, mental and environmental factors that over-simplification inevitably becomes misleading. It is true that when a preparation is offered for sale the condition of ill health for which it is intended must be indicated. On the one hand many diverse functional and organic troubles are accompanied by outward manifestations of indispositions of an exceedingly similar character and number; on the other hand reports of pathological, physical or psychical conditions are almost necessarily only presented accurately in technical or scientific form and are then not normally understood by the public. Thus the only symptoms to be suggested to the public for self-diagnosis are those which are specific for the trouble for which the remedy is offered and which will not induce any member of the public to think that his symptoms mean that he has that particular trouble when in reality he is not or is not likely to be suffering from it.

B. 33. **Scare Advertising.** Self-diagnosis, self-medication should not be provoked by use of fear-inducing copy. It is improper to create alarm that, unless the food or drug in question is used by the reader of the label or advertisement, his health will suffer, or that he cannot enjoy full health or nutritional health.

B. 34. **Laboratory.** The term "laboratory" or "laboratories" implies scientific personnel, equipment and operations. Factories or premises should not be described as laboratories, on labels or in advertisements, unless bona fide laboratories are maintained and actual laboratory operations are carried out by or under the direct supervision of qualified scientific personnel.

B. 35. **Honest Conviction.** The honest conviction of the seller of an article of its merits or mode of action is no substitute for definite knowledge obtained by adequate and proper tests.

B. 36. **Illustrations.** Pictures and charts are a much used and valuable aid to advertising but should not be so employed as to exaggerate, to mislead, or to misrepresent; where pictures purport to represent actual people they should portray the actual people concerned; representations of professional people or of laboratories or apparatus having no direct connection with the product and used to create "atmosphere" should not be used particularly where such pictures are not intelligible to the general public; "before and after" pictures are to be avoided; pictures of ingredients not present in the article labelled or advertised are deceptive; pictures leaving the impression that the article labelled or advertised is another article are deceptive; where labels are pictured they should be current labels. Pictures of fruits on labels or advertisements of imitation or artificial goods are usually objectionable.

B. 37. **Atmosphere.** The creation of vague, mysterious, provocative, or otherwise unusual atmospheres that intrinsically have no relation to the product or its genesis should be avoided.

B. 38. **Questionnaires.** These are used to obtain from selected groups of people their opinions upon various subjects as suggested by the questioner. In most cases the opinions thus obtained are of no scientific consequence or significance even when they can be classed as case reports.

B. 39. **Guarantee.** The use of the word guarantee presents difficulties inasmuch as the impression of almost inevitably successful results is created. Today the word is usually associated with an offer to return purchase price and better words to use are offer or agreement.

B. 40. **Asterisks.** Asterisks are sometimes used in labelling and advertising to direct attention to what is frequently an obscure statement explaining that a featured statement is not exactly what it appears to be. Such a device is misleading, for a false or misleading statement cannot be held to be correct on account of a later explanation.

B. 41. **Abbreviations.** Abbreviations, including initials, are generally uninformative and may be misleading. Mandatory label information may not be abbreviated except as allowed by the Regulations. Official abbreviations may usually be used except for the name or for the list of ingredients required on the label.

B. 42. **Descriptives.** There is a certain category of words which are now, by general understanding, avoided in food or drug claims. No words or phrases implying that a food is perfect or that a drug is a cure are permissible. Words such as balanced or prescribed, should be avoided as they are often misleading. After these come the superlatives such as best, those of unusual emphasis such as sensational, "miracle" words, and the comparatives such as better. They are all likely to be regarded as false, exaggerated, misleading, or deceptive except in certain circumstances where the user may be qualified to use his own judgment. Subjectively the user himself can well judge of flavour, texture, appearance, and recipe value, for example, so that it is rarely that the administration enters into these fields.

B. 43. **Appropriated or Inferred Claims.** The device of so constructing a claim for a product or its use that the merits of another article with which it may perhaps be used are directly, indirectly, or by hurried reading appropriated to the product itself is deemed to be misleading.

B. 44. **Health, Healthful.** No food in itself will restore health, and the same is true of a drug. No individual food or drug should be described as health food or health drug, except that Health Salts is sanctioned by long usage as a euphemism for a saline laxative. Therefore the words Health, Healthful should be avoided in contexts where it is implied that health will be obtained through consumption of the product. All foods are consumed in part to maintain nutritional health, a term which is not synonymous with general health, and drugs are taken to remedy a specific state of ill-health. Some foods may be better nutritionally than others but none will give or assure health.

No objection is taken to the word "Health" in the statement "Health and Beauty Aids" when displayed in stores or in an advertisement.

B. 45. **Comparisons.** Comparisons with other articles, or comparisons with selected factors of other articles, are often misleading, sometimes thoroughly deceptive. Comparisons should avoid creating doubt about other perfectly acceptable foods or drugs. The comparisons are sometimes incomplete in the sense that they do not usually call attention to factors or properties of the other article which are superior to those of the article being advertised. It is misleading to compare solid with liquid on a weight for weight or volume for volume basis, to compare an article consumed in small quantities with one consumed in large quantities, or to compare one taken occasionally with one that is used regularly.

B. 46. **Dangling Comparatives.** Such words as better, richer, imply a comparison, often without indicating the basis of comparison. To prevent deception it ought to be said what the product is better or richer than, and in what particular, and even then there may be no absolute over-all justification. If the product is an improvement over one previously made by the same firm that is what should be indicated.

B. 47. **Strength; Potency.** Before such terms as Double Strength, Triple Strength, can be used there must be a stated or recognized normal strength or potency. In cases relating to drugs of standard strength or potency there may be objection to offering drugs of strength or potencies differing from those of the standard.

B. 48. **Concentrated; Concentrate.** These are terms that should be restricted to their proper uses. For instance they should be employed with care when implying extraordinary nutritional or therapeutic values. Often the description should be evaporated or dried and the effect of concentration is lost when it is realized that liquid has to be supplied either directly or in the daily diet in just the same amount as has been evaporated. Mixtures over the composition of which the manufacturer has full control ought not to be described as concentrates or concentrated. Mixtures of dried foods or drugs are not concentrates. Because a mixture is strong it is not thereby a concentrate unless it is concentrated from the beverage as in concentrated orange juice. Again a heavy syrup is not concentrated or a concentrate. Foods restored to their original moisture content or other condition, e.g., fruit juices, should be clearly labelled "Reconstituted".

B. 49. **Rich in; High and Low.** To say that an article is rich in any factor implies some normal amount that it is richer than and so inevitably introduces a comparison. The terms high and low also imply a comparison and should be avoided.

An article may be naturally rich per se in a particular factor but, because of the small quantity of the article used, the contribution of that factor to the user may be inconsequential, so that to describe the article as rich is misleading. Where the article is manufactured and the amount of any factor is at the discretion of the manufacturer a quantitative statement can be given. For vitamins the regulations limit the ways in which the vitamin strength is to be stated and additional statement such as rich, or high only serve to confuse the purchasers. "Rich" when used in connection with flavour, appearance, texture, and the like can be judged by the user and the administration, as previously stated does not usually enter this field.

B. 50. **Geographical Terms.** Geographical adjectives indicate that the goods so described are bona fide products of the place named except in such cases as those in which the geographical term has lost its significance, for example, Hamburg Steak, Spanish Onion, Boston Beans. Where the goods are not products of the place named and where such description may be considered deceptive or misleading, the product must be labelled in such a way as to remove the deception.

B. 51. **Imported.** "Imported" can only mean that the product, as a unit, is brought in from another country and is sold in Canada without modification except for packaging and the like. If ingredients are actually imported they can be so described.

B. 52. **Home-Made.** Articles made in commerce cannot be described as Home-Made. "Home-Made Style", if true is acceptable as is "Home-Made Flavour" or "Home-Made Appearance".

B. 53. **Nature.** "Nature", "Mother Nature", "Nature's Way" are terms generally misused in that actually Nature is impersonal and does not especially favour humans above any other living or dead components of the universe.

The most complicated chemical processes follow Nature's laws. Animals, plants and minerals were not placed on Earth for the sole use of man and their composition is not specially designed to be exactly right for man.

B. 54. **Natural.** Whether there is justification or not the public seems to regard a "natural" article as of greater worth than a processed one. There are few foods or drugs which are so devoid of processing as strictly to justify the description "natural". Many, however, are obtained from natural sources alone with a minimum of processing, so as to retain most of the useful constituents. When describing drugs, the term "natural" usually means that the ingredients are of vegetable origin. That is what should be said. It is improper to say that a drug acts naturally; all drugs act by artificial stimulation or assistance to the functions of the human body.

B. 55. **Beverages with Nutritional or Medicinal Claims.** These will be treated as foods or as drugs requiring statutory statements of composition. These products must have the nutritional or medicinal properties claimed.

B. 56. **Packages.** Packages for foods or drugs, must not be deceptive in design, fill, or any other manner. Illustrations and colored wrappings should not be used in any manner which misleads the consumer as to the true nature or content of the package. The Drug and Cosmetic Regulations set out appropriate measurements for cartons containing collapsible tubes.

B. 57. **Negative Statements.** In general, statements indicating the absence of certain ingredients serve no useful purpose and in fact, are often misleading in that they infer that other quite acceptable products do contain these undesirable ingredients without the consumer being aware of it, which is not usually the case. Negative statements will be considered in the light of Sections 5 and 9 of the Act and may only be tolerated when they are factual, informative and not misleading. Examples of negative terms which are considered to be informative are "non-irritating", "non-staining", "does not burn", "does not sting", "non-laxative", when they are true (See also Section C.13, Dietetic Foods). Others such as "non-toxic", "non-poisonous" are considered to be misleading. These are dangerous because they imply that the particular product is completely harmless, even if taken in overdose, or accidentally ingested in large quantities even by children. "Non-narcotic" is misleading because it infers, contrary to fact, that certain drugs that are freely available may contain narcotics.

The Directorate feels that products should be sold on their own merits and not by comparing them with other products which contain perfectly acceptable ingredients.

C. 1. **Labels: Position of Mandatory Statements.** The main panel of the label is that panel which is usually displayed to the public, and it carries the brand name, if any, the common name of the food and a correct statement of net contents. (See Section C.2 for more explicit information regarding the declaration of net contents). In addition, there are statements throughout the Regulations which are also required on the main panel. The list of ingredients, the declaration of designated preservatives by name, added colour, imitation or artificial flavour, and other mandatory information must appear grouped together on the main, or any, panel other than the bottom of the package.

The name and address of the manufacturer should appear on any panel other than the bottom of the package.

All mandatory information must be clearly and prominently displayed and readily discernible to the purchaser or consumer. In general, information in letters less than $\frac{1}{16}$ inch in height is not considered to be clearly and prominently displayed.

C. 2. **Net Contents.** The Regulations require that a correct declaration of net contents in terms of weight, measure, or number, whichever is customarily used in stating the quantity of the type of food referred to, appear in bold face type on the main panel of the label in close proximity to the common name. The size of the net content declaration is related to the area of the main panel. Close proximity means immediately above, below, to the right or to the left of the common name without intervening printed, written or graphic matter.

The position and size of the statements of net contents are exempt from the requirement of the Regulations if the manner or declaration is prescribed or described by any other Federal or Provincial statutes or Regulations made thereunder.

The weights and measures official in Canada under the Weights and Measures Act must be used to express the net contents.

C. 3. **Compounds; Mixtures.** Foods offered as compounds or mixtures will be considered in the light of Sections 5 and 6 of the Act. Compounds or mixtures that are not deemed to violate the provisions of these Sections must contain at least 51 per cent of the predominating ingredient after which they are named and must carry a complete list of ingredients in descending order of their proportionate content with the percentage proportion of the predominating ingredient being stated. The word "compound" or "mixture" must be an integral part of the name of the food and must be no less legible or conspicuous upon the label or in any advertisement than the name of the predominating ingredient.

C. 4. **Imitations; Substitutes.** Foods offered as substitutes will also be considered in the light of Sections 5 and 6 of the Act. Such foods that are not considered to violate the provisions of these Sections must, with the exception of

imitation flavouring extracts, be labelled with a complete list of ingredients in descending order of their proportionate content. The word "imitation" or "substitute" must be an integral part of the name of the food and must be no less legible or conspicuous upon any label or in any advertisement than the name of the food being imitated or substituted.

C. 5. **Pure; Genuine.** Terms such as Pure, Genuine, and the like when used must be employed with care. They should not be used in advertising and labelling to refer to Imitations or Substitutes. Foods or ingredients in foods may be described as pure when the description is true.

C. 6. **Meat Extract.** It is false or misleading to claim or suggest that because an edible extract is derived from meat it has the concentrated properties of the meat from which it is derived or that it is nutritionally significant for the purposes for which meat is consumed.

C. 7. **Chocolate and Cocoa Products.** In advancing claims for foods containing chocolate or cocoa it is necessary to consider the contribution of the actual amount of chocolate or cocoa consumed and to avoid including claims for the properties of the accompanying food as if they belonged to the chocolate or cocoa.

Chocolate and Cocoa are distinctly different products in that chocolate has a considerably higher cocoa-fat content, and thus products which contain the lower fat cocoa should not imply that they contain chocolate. There is no objection to the use of the word "chocolate" to indicate flavour in cases where cocoa is used.

C. 8. **Milk.** Milk unless otherwise designated is taken to mean Cow's milk. The standards for fluid milk are set, and enforced, by local authority, and milk that meets these standards should not be described in more glowing terms than whole milk. Such terms as creamy, higher butterfat may only be used to describe milk that is substantially higher in butterfat than standard milk.

Milk is not commonly hard to digest or unpalatable to children and others and it should not be implied that it is in the attempt to promote the sale of treated or modified milks, or of products to be made or used with milk. There is a reasonable limit to the daily quantity of milk or milk products that should be consumed, for an excess displaces other required foods from the diet, therefore the advice "Drink more milk" should not be carried to the extreme. Milk should not be used as a vehicle for another food for which nutritional claims are advanced without giving at all times, the correct proportionate value of the contribution made by the milk.

C. 9. **Mineral Waters.** These are waters for which mildly hygienic or therapeutic properties based on their mineral content are claimed. In general the claims should not go beyond the use of the waters as adjuncts to a dietary regime and should avoid such a level of claims as would result in the water being classed and dealt with as a drug.

C. 10. **Butter.** Care has to be exercised in the use of the word "butter" in the name of a food. Where it refers to texture, form, and the like, and it is made perfectly clear that it does not mean a content of butter there is no objection. It cannot safely be used upon an article that is, or has been made in part of butter unless the article in fact contains butter. Peanut Butter is an example of a non-misleading use of the word.

C. 11. **Malted.** A food is not properly described as malted because of the addition of malt extract. "Malted" means that the carbohydrate has been modified by suitable treatment with the diastase of malt. Unless such treatment has been given "malt flavoured" is the appropriate term to use.

C. 12. **Digestibility.** Digestibility in its popular sense refers to the ease or comfort with which a food is assimilated and to the absence of distressing after effects. References in technical literature to a coefficient of digestibility have a quite different meaning and hence cannot be used to connote digestibility in the popular sense.

C. 13. **Dietetic Foods.** Foods which are specially prepared or manufactured for a special dietary purpose may be described as "Dietetic". When a special dietary use is implied on the label or in an advertisement for a food, the type of diet must be stated on the label.

Foods recommended for either calorie reduced (restricted) diets or for weight control diets should be significantly reduced in calories when compared to other foods normally encountered in the same class. A statement of caloric content in calories per 100 grams of the product is required on the label of such foods. Foods recommended for sugar, carbohydrate or starch reduced (restricted) diets should also be significantly reduced in carbohydrates when compared to other foods normally encountered in the same class. The claim "made without (added) sugar", is acceptable, if factual. The claim "sugarless" or "sugar free", may only be made if the product does not contain carbohydrates.

The percentage of sodium that a food contributes to the daily diet must be significantly reduced in order to be recommended for sodium restricted diets. A declaration of the sodium content in milligrams per 100 grams is required on the label of such foods. The claim "salt free", and "saltless" are only acceptable if the foods contain no Sodium salts. The claims "made without salt", "made without (added) salt", and "no salt added", are acceptable if corresponding products are usually made with salt (NaCl).

Natural foods, that is, foods which have not been processed or which are processed without any special modification but which happen to contribute significantly little of a component for which a claim is made are treated in the same manner as dietetic foods in so far as labels and advertising are concerned, except that they cannot be described as "Dietetic Foods".

Such terms as "high" and "low" when used to describe ingredients or substances found in or forming part of a food are considered to be misleading since such terms introduce a comparison and invariably create a doubt

regarding other perfectly acceptable foods. In view of this, such terms as "low in calories", "low in Sodium" and "high in Protein" are not acceptable.

C. 14. **Tonic Foods.** No food should carry claims to be effective as a tonic. All foods play a part in relieving hunger and provide calories; some being utilized rapidly and others over a longer period. Accompanying the ingestion of food when hungry, or after work, there is often a sense of well-being. This is common to all foods, however, but it is not a tonic effect.

C. 15. **Medicated.** When a food is described as medicated, it, by definition under the Act, becomes a drug in addition to any other properties it may have and must also be labelled and advertised as is required for a drug. It should possess observable therapeutic properties. If the article is to be used in the way that a food is used, the effects of steady or long-continued ingestion of the medication becomes paramount consideration.

C. 16. **Balanced.** No single food can be thought of as balanced or of being able to balance a meal or diet. Nutritional balancing can only occur in the diet as a whole, in a general sense, and over a reasonable period of time.

C. 17. **Laxative Foods.** Like any other laxative, foods providing extra bulk or roughage to produce bowel movements may become habit forming and the diet should preferably be corrected rather than to continue to rely on such foods. Adequate information should be afforded prospective users to enable them to determine if their constipation is in fact due to deficient bulk together with a warning that if the constipation is due to one or more of the many possible causes increased bulk or roughage may be harmful. The following is reproduced from "Healthful Eating": "With just a little encouragement in eating a few "bulky" foods, and by responding regularly to the call for bowel evacuation the body will develop a health rhythm of bowel movements". The rhythm may vary from three or four times daily down to once in two or even three days and still be within the normal limits. Any change in a person's rhythm for one or even several days is not to be considered alarming especially if there has been a change in eating or living habits to account for it. By far the best approach to such deviation from the normal rhythm is adjustment of the diet – not violently by eating a lot of some food known to be laxative for the person concerned, or by eating a lot of "roughage", but gently by substituting for example, prunes for peaches, brown bread for white, salads for heavy meals. Increasing the use of vegetables rather than meats, eggs, and milk is a good general rule.

The above comments will be helpful for most cases labelled "constipation". Exercise, correct posture, regular habits, avoidance of concern over the subject, and avoidance of dosing with pills and nostrums, will all help to maintain bowel movements within normal limits of variation.

C. 18. **Alkaline; Alkali forming.** Claims that a food is alkaline, or alkali-forming, are misinterpreted by the general public, and often by the copy writer, as having something to do with stomach acidity or blood acidity especially

when words such as acidosis, acidity, or acid are used. Though popular to a degree in scientific circles some years ago "alkali-forming" is now regarded as of only theoretical interest.

C. 19. **Non-Fattening Foods.** No food should be claimed to be non-fattening.

C. 20. **Energy Foods.** Energy claims for foods are not understood by the public and often not even by the advertiser. The energy or caloric value of a food is a scientific conception which has nothing to do with the popular conception of energy in the sense of being energetic, having "pep", vitality, vigour, activity or in the other sense of power, strength, and endurance. Some advertisers have shown a tendency still further to extend this lay conception of energy to embrace brightness of intellect and success at school, games, and so forth, and to the prevention or relief of fatigue. It is a sober fact that all these conditions depend on many factors including, freedom from disease, heredity, environment, mental state, upbringing and so on, in which no food can possibly be expected to have total significance. As far as the technical concept of caloric energy is concerned all foods can be energy foods from their content of fat, protein, and carbohydrates of which fat is the most potent, carbohydrates and proteins being less potent and each affording about the same number of calories. The terms "food energy" and "quick food energy" are not regarded as misleading where they are appropriate. The term "energy food" is not really an appropriate one. Some foods e.g. starches or sugars, predominantly have no other function than to satisfy food energy requirements.

C. 21. **Sustained; Lasting.** Along with the claims for quick food energy provided by predominately carbohydrate foods there often appears a claim for such food energy to be lasting over many hours of hard work or play. The carbohydrate foods are, however, utilized relatively quickly under these conditions so that the claims may be in conflict.

C. 22. **Fresh.** The unmodified term "fresh" is considered to mean unfrozen or unpreserved by any method. Cold-storage foods, as distinct from frozen foods, are generally considered as fresh foods. "Fresh-frozen" is considered to mean fresh food that has been frozen at the earliest possible stage in harvesting or processing. The merits of a claim for fresh flavour can be judged by the consumer.

C. 23. **Cream; Creamy.** These words should not be used in circumstances where they can in any sense relate to or leave an impression of a cream (butterfat) content unless there is an actual, significant amount of cream supplied. When used to describe texture, appearance, consistency, and the like the context should make this clear. "Chocolate Cream" and certain other uses of "cream" are tolerated on account of long usage.

C. 24. **Beverages employing the Name of a Fruit.** There are standards set by regulation for fruit juice, and beverages identified with the name of a fruit must be so labelled and advertised as to distinguish them clearly from the

standard articles. If fruit juice is used in part and is present in significant quantity its appropriate mention is not objectionable; care should be taken about using an illustration of a fruit and it should not be used where the flavouring is more artificial than natural; the use of the suffix "ade" is acceptable or the statement that the drink is flavoured or made in part with fruit juice.

Where artificial flavours are used there has to be a corresponding declaration in the list of ingredients but this declaration in itself is not necessarily sufficient to offset the impression that may be conveyed by the use of the fruit name. When true fruit does not greatly predominate illustrations of fruit cannot be other than deceptive.

C. 25. **Food Fads.** New facts about foods are accumulated and verified by qualified research groups, and are released for general information only after their truth and usefulness have been established. Food Fad promoters, on the other hand, are not usually qualified to expound upon new and special virtues of food products. Advertisements for such food items as Molasses, Yoghurt, Cider Vinegar, Wheat Germ must not imply curative or corrective powers which are not considered to be a property of the food item.

D. 1. **Labels: Position of Mandatory Statements.** The proper name or the common name of the drug must be carried on the main panel of the label. The name and complete address of the manufacturer, the declaration of net contents, the list of medicinal ingredients and directions for use do not have to appear on the main panel, but can be put anywhere on the label provided they are prominently displayed thereon.

Mandatory statements will not, as a rule, be accepted if they appear on the bottom face of a container because they are not readily discernible under customary conditions of purchase and use.

A list of medicinal ingredients is not usually required where there is an official standard for the drug. It can sometimes be regarded as misleading to call attention to one or more ingredients of such standard articles. However, in certain instances the regulations require the declaration of specific ingredients.

D. 2. **Prescription.** The meaning of prescription in relation to the Food and Drugs Act is defined and rules out the use of this word in connection with a prepared, packaged article for self-diagnosis and self-medication. The verbal forms prescribe, prescribed, etc., are similarly ruled out.

"Now available without prescription" is deceptive and misleading because it implies that the drug has been proven so safe that it has been removed from the prescription list, and is freely and widely available for self-medication. In nearly all cases the drug was never on the prescription list. Furthermore, drugs deleted from Schedule F to the Act are usually transferred to the Table of Limits of Drug Dosage for Adults with zero limits, and so may not be advertised to the general public.

D. 3. **Sexual Impotence.** A claim to treat sterility is not distinguishable from a claim to treat sexual impotence. Euphemistic expressions such as – manly power, virility, for wife and man, etc. are likewise related to sexual impotence and are therefore objectionable.

D. 4. **Disorders of Menstrual Flow.** The ban placed by Schedule A on the sale and advertising to the general public of treatment for disorders of the menstrual flow is directed against amenorrhea and retarded menstruation. It does not apply to analgesics to assuage pain that sometimes occurs at menstruation, or to appropriate medication for the menopause, leukorrhea and dysmenorrhea.

Mixtures of purgatives and so-called emmenagogues can only be looked upon as designed to overcome the disorders of menstrual flow. They are not regarded as being appropriate to relieve menstrual pains or the symptoms of the menopause.

D. 5. **Liquor Habit.** Preparations to overcome the liquor habit are regarded as treatments for alcoholism. Alcoholism is a Schedule A disease and therefore such preparations are not allowed to be sold and advertised to the general public. As a general rule this does not include preparations offered as a treatment for the after effects of drinking.

D. 6. **Vermin and Infection Control.** A drug also includes any material that may be used for disinfection in premises in which food is manufactured, prepared, or kept or for the control of vermin in such premises. All such material is inherently poisonous. According to the degree of hazard to health involved the sale of such material may be prohibited or the conditions of its sale may be so defined as to offer a protection against the hazard.

Household and industrial cleansers and bleaches for which germicidal and disinfectant claims are made do not fall under the authority of the Act unless they comply first with the definition of a drug in Section 2(f). The slight bactericidal activity which might be claimed for such products is only secondary and incidental to their cleansing and bleaching power, and would not place them in the category of drugs. However, if drug type claims are made for these products, such as treatment of athlete's foot, prevention of disease by reducing the number of bacteria, etc., they are regarded as drugs and their labelling and claims should be in compliance with the requirements of the Act and Regulations. Pediculosis (Lice) is considered to be a disease and products which claim to treat it are drugs and must be labelled accordingly.

D. 7. **Radio-active Preparations.** These drugs are governed by special regulations which require that they be manufactured under licence. Special labelling requirements also apply. They are designed to be used only under the supervision of specialists because they can cause harm to the operator as well as to the patient if improperly manipulated.

Unlicensed preparations which would contain enough active material to be therapeutically significant are, per se, too dangerous for self-medication. If they are of low activity, or possess no activity, they are fraudulent. Therefore, only licensed preparations can be advertised or sold.

D. 8. **Rheumatism; Arthritis; Neuritis; Lumbago; Allied Conditions.** The successful treatment of these conditions depends on early professional diagnosis, competent and continued treatment under medical advice and supervision. No preparation may be advertised as a treatment for these conditions or as capable of restoring normal or complete function of joints and muscles, or to reduce swelling and inflammation, or to correct or prevent deformities, or to restore movement to stiff or crippled joints and muscles.

Recognized analgesics, taken internally in proper doses, may be offered as a help in relieving or temporarily alleviating rheumatic, arthritic or neuritic pains. Local applications of rubefacients or counter-irritants, especially when applied with massage, may also help to relieve pain at the site of application.

The pain of allied conditions such as lumbago, sciatica and bursitis may also be relieved by the same method. All advertising copy should make it clear that these products are for the relief of pain only. Therefore, the word "pain" should be given adequate prominence when appearing in expressions like "pain of rheumatism, arthritis or neuritis". The best way to avoid an improper connotation is to use such words as rheumatic pain, arthritic pain and the like.

D. 9. **Allergies; Asthma; Hay-fever.** Certain drugs will tend to relieve the distressing outward manifestations of these troubles, such as the wheezing, engorgement, paroxysms that occur in the attacks or spasms and this is all that may be claimed. Since allergy is not primarily due to functional derangement or to bacterial action, drugs are not to be expected to relieve the causes. Warnings against continued use may be necessary.

D. 10. **Colds.** In general no preparation yet can claim to stop, abort, prevent, or lessen the frequency of colds. There are drugs that may be of value in relieving symptoms associated with colds, but as none of these is known to have any effect on the virus which is still believed to be the causative organism claims should be restricted to the relief of only such of the symptoms as the preparation can be depended on to combat.

Influenza is a Schedule A disease. "Flu" is taken to be the abbreviation of Influenza and may not be used as a synonym for the common cold. Virus Cold is also misleading in that it infers that the drug advertised is useful or effective against the virus.

D. 11. **Coughs.** Coughs may be associated with more serious conditions so that cough treatments should specify carefully the necessary limitations and certainly should not leave any inference that they are of any value for the condition causing the cough. One of the symptoms of certain types of colds is the cough and there is a number of preparations which are palliative of such coughs. Most of these preparations should be offered only for "Coughs due to Colds".

Objection is taken to the claims "Stop Cough", "Freedom from Cough" and similar claims, because they connote complete and permanent supression of the cough and get very close to meaning a cure. A statement that a product provides up to 6 hours of relief from coughs is misleading unless a controlled release dosage form is used. The term "prolonged relief" would be more suitable.

As a rule Cough Drops contain medicinal ingredients. They are classified as drugs and should be labelled accordingly. Since they are recommended for internal use, the lot number should be carried on the label.

D. 12. **Cathartics; Purgatives; Laxatives; Aperients.** These are employed to relieve temporary or occasional constipation and are not treatments designed to remove the cause of continued or habitual constipation. They should not be offered for other than temporary, short-term use, or in such a manner as to induce the public to acquire a dependence upon them, for all cathartics are regarded as potentially habit-forming. Laxatives cannot be claimed to produce a "natural" motion or to act in the commonly accepted meaning of "Nature's Way"; nor do they produce a normal action, restore regularity or aid Nature to regulate the system or purify the system. Since action is usually on the lower intestine, claims to eliminate all poisons, thoroughly cleanse the intestinal tract or the body, the system and so forth, have little or no justification. It must be remembered also that many of these preparations are irritant, and contraindications for their use under certain conditions are in order.

D. 13. **Liniments.** Liniments for relieving aches and pains have their limitations especially as to being efficacious for all types of pain, for deep seated pains and as to their degrees of penetration. There is no selective action in a rubbing preparation which concentrates it at the site of the pain.

D. 14. **Eye Medicines.** These will not correct functional errors of vision nor pathological conditions, strengthen vision etc., but are only eye washes, which will refresh, assist in removing dust or in clearing up minor irritations.

D. 15. **Skin Troubles.** In general, claims for skin preparations should not go beyond the treatment of minor skin troubles. The treatment of most skin diseases and troubles is uncertain even in skilled hands. Preparations for such things as eczema, psoriasis, itch, scabies, etc., should be advertised with restraint, particularly as to psoriasis. Eczema too is not a specific term and is most intractable in treatment so that claims for preparations could very well be restricted to a temporary improvement of the skin when used as directed.

D. 16. **Athlete's Foot.** Claims for a drug offered in connection with athlete's foot should be quite moderate and, as far as present knowledge goes, confined to surface conditions and to the soothing of irritations. Athlete's foot may be caused by one or more of several fungi or by bacteria and may be aggravated by secondary infection. Remedies useful against one causative agent may be of little use against another. Strong medications may make conditions worse. There is an ever present chance of reinfection.

D. 17. **Sinus.** Because the sinuses are very difficult to reach, external preparations for "sinus trouble" are generally useless. Both external and internal preparations may afford temporary relief from pain and discomfort, but even this is doubtful particularly if the sinus is not drained.

D. 18. **Liver Remedies.** Most of the so-called liver remedies are powerful laxatives. Product names that include the word "liver" are tolerated in certain existing products only because of their long usage.

As far as present knowledge goes, the secretion and flow of bile is the only function of the liver that perhaps can be stimulated by drugs and only a few are believed to be active at all in this respect. Laxative preparations that contain suitable quantities of appropriate cholagogues or choleretics may be represented as helping to stimulate the flow of bile in addition to the usual claims for a laxative.

These products may not be represented as relieving diseases of the liver and objection is taken to vague general terms which imply action on the liver as a whole. They are incapable of communicating to the user extra energy, pep or vigor, and therefore, references to their benefits should be restricted to the temporary relief of discomforts due to constipation associated with insufficient bile. Such terms as liver troubles, inactive or congested liver are frowned upon.

D. 19. **Kidney and Bladder Remedies.** Practically all the so-called kidney remedies are diuretics. They are of limited usefulness and may be dangerous in certain cases. They do not flush out the kidneys nor do they remove impurities from the blood, purify the blood or relieve rheumatic or arthritic pains or pain in general. They may not be represented as useful in the treatment or prevention of any form of disease or kidney ailment. Claims must be limited to their effect in helping to increase the flow of urine thus relieving irritations of the bladder and urinary tract and resultant backache or discomfort. Particular care must be taken to avoid any connotation, implication or suggestion that diuretics are effective against urinary calculi, kidney stones or bladder stones.

D. 20. **Adequate Directions For Use.** All drugs must bear adequate directions for use. Usually this will include the conditions for which the drug is recommended (except Schedule A conditions). Where directions are lengthy, they may be shown on a package insert provided that notice of this is given on the label in a manner such as "For Directions See Enclosed Circular".

D. 21. **Results of Treatment.** When a preparation's usefulness is largely confined to the alleviation of distress and discomfort accompanying a condition, this should be made clear in any advertising material. In many cases a further explanation of the temporary nature of the relief is necessary for a complete understanding of the value of the product.

No drug should give assurance of results either by indirect inference or by use of a name which implies a cure.

D. 22. **New Drugs.** Specific regulations list the requirements which must be fulfilled before a new drug may be placed on the market in Canada. The safety of the drug must be assured before it may be sold or advertised for general use.

The various forms which must be completed, as well as detailed information about new drug applications may be obtained from any Food and Drug Office.

D. 23. **Blood Purifiers.** These preparations are usually laxatives and diuretics with the addition of iodides and vegetable extracts. They have no recognized value in purifying or cleansing the blood or in treating diseases of the skin allegedly due to impure blood. All such representations by product name or by actual claims are regarded as false and misleading. Their usefulness is strictly limited to their laxative and diuretic properties.

D. 24. **Veterinary Drugs.** The definition of a drug under the Act includes drugs for veterinary use and therefore these are subject to the requirements of the Drug Part of these Regulations. In addition to the general drug regulations these preparations must meet the requirements of sections pertaining to veterinary drugs in the Food and Drug Regulations.

D. 25. **Safety of Drugs.** No drug or drug preparation should be represented as safe or harmless.

E. 1. **Cosmetics.** Cosmetic, means any material represented for cleansing, improving, or altering the complexion, skin, hair, or teeth, including deodorants and perfumes.

In general, a cosmetic becomes a drug when therapeutic claims are made for the product or when it contains materials considered to have therapeutic action, or when it is considered to be potentially dangerous to health.

E. 2. **Hair Preparations.** Preparations purporting to treat Dandruff are drugs.

Shampoos to remove dandruff particles and lotions or creams designed to improve the appearance of the hair are considered to be cosmetics.

Hair removers must not claim permanency of results and should not claim that the preparation is safe or harmless. Hair removers, except when accomplished by careful Electrolysis, do not kill the hair root.

There is no preparation yet known that can cause hair to grow on bald heads. Some preparations may help to retain existing hair but advertising should not infer that they can produce new hair growth.

The regulations demand cautionary statements on the label for some hair dyes and for preparations when a hazard exists.

E. 3. **Cosmetics Containing Sex Hormones.** Claims made for cosmetics containing sex hormones are limited to such claims as are acceptable only for the use of a product as a cosmetic. Where claims made indicate that the preparation has a systemic effect the preparation is then classified as a prescription drug and no advertising to the general public is allowed. Claims such as development of the female breast, rejuvenating, revitalizing, regenerating, and the like are, therefore, not permitted in advertising to the general public.

E. 4. **Dentifrices.** Certain dentifrices with anti-bacterial, anti-enzymatic, anti-acid, or anti-decay formulations, which have been shown to be effective in reducing the incidence of dental caries, are considered to be drugs. Other preparations which are marketed for cleaning the teeth and freshening the breath are treated as cosmetics. The causes of most periodontal diseases are not firmly established but there is evidence that several factors, some local and some systemic, are involved in addition to which local irritants such as calculi, food impaction and rough filling margins are frequently present. A dentifrice will not remove these local irritants nor will it influence the systemic factors.

Dentifrices and the like cannot be depended upon to tighten teeth, stop bleeding gums, or treat pyorrhea, but may be expected to assist the tooth brush in exerting a mechanical action in removing food and bacterial plaques from tooth surfaces.

F. DEVICES

F. 1. **Devices.** Devices are covered by the Food and Drugs Act, which prohibits their sale or advertisement in a misleading or deceptive manner. They may not be advertised to the general public for the treatment or prevention of any of the Schedule A conditions.

G. MISCELLANEOUS

G. 1. **Trade Information Letters.** From time to time the Food and Drug Directorate issues Trade Information Letters directly to the trade and others concerned with various commodities. These letters deal largely with matters of interpretation. They are designed to assist in the enforcement of the Act by providing information that will prevent infractions so that punitive action will not become necessary. These letters are supplied free of charge, and may be obtained from

Food and Drug Directorate,
Department of National Health and Welfare,
Tunney's Pasture,
Ottawa, Ontario.

G. 2. **OFFICE CONSOLIDATION OF THE FOOD AND DRUGS ACT AND REGULATIONS.**

An Office Consolidation of the Food and Drugs Act and Regulations is available in loose leaf form. This together with an amendment service to keep your copies up to date, may be purchased from the Department of Public Printing and Stationery, Ottawa, Ontario, for a moderate fee.

G. 3. **Food and Drug Offices**

Regional and District Food and Drug Offices are located in the following centres:

HALIFAX, N.S. – Superintendent, Inspection Services,
Food and Drug Office,
Ralston Building,
105 Hollis St.,
P.O. Box 605,
Telephone 423–8139.

CHARLOTTETOWN, P.E.I. – Food and Drug Inspector,
5th Floor, Confederation Building,
P.O. Box 1311,
Telephone 894 – 8632.

SAINT JOHN, N.B. – Food and Drug Inspector,
Room 517, New Customs Building,
P.O. Box 396,
Telephone 3–3780.

SYDNEY, N.S. – Food and Drug Inspector,
Federal Building,
P.O. Box 324,
Telephone 564 – 6158.

ST. JOHN'S, NFLD. – Food and Drug Inspector,
Sir Humphrey Gilbert Building,
P.O. Box 596,
Telephone 578–7262.

MONTREAL, QUE. – Superintendent, Inspection Services,
Food and Drug Office,
Suite 800, Customs Building,
400 Youville Square,
Telephone AVenue 8–4217.

OTTAWA, ONT. Food and Drug Inspector,
Food and Drug Building,
Tunney's Pasture,
Telephone 9–2–2979.

QUEBEC, QUE. – Food and Drug Inspector,
375 Dorchester St.,
P.O. Box 3251,
St. Roch,
Telephone LAfontaine 2–6166.

TROIS-RIVIERES, QUE. – Food and Drug Inspector,
Post Office Building,
P.O. Box 1123,
Telephone FRontenac 4–3044.

SHERBROOKE, QUE. – Food and Drug Inspector,
Room 232, 315 King St. W.,
P.O. Box 1120,
Telephone LOrraine 2–0944.

TORONTO, ONT. – Superintendent, Inspection Services,
Food and Drug Office,
Arthur Meighen Building,
55 St. Clair Ave., East,
Telephone WALnut 925–2245.

BELLEVILLE, ONT. – Food and Drug Inspector,
New Federal Building,
Pinnacle St.,
P.O. Box 93,
Telephone WOodland 2–3011.

HAMILTON, ONT. – Food and Drug Inspector,
National Revenue Building,
150 Main St. W., at Caroline St.,
Telephone JAckson 2–3800.

KITCHENER, ONT. – Food and Drug Inspector,
Dominion Public Building,
Duke and Frederick Sts., P.O. Box 33,
Telephone SH2–6197.

WINDSOR, ONT. – Food and Drug Inspector,
Dominion Public Building,
Telephone CLearwater 2–1674.

LONDON, ONT. – Food and Drug Inspector,
Dominion Public Building,
457 Richmond St.,
P.O. Box 504,
Telephone GEneral 4–2545.

SUDBURY, ONT.	– Food and Drug Inspector, 3rd Floor, New Federal Building, P.O. Box 564, Telephone OSborne 4–1032.
WINNIPEG, MAN.	– Superintendent, Inspection Services, Food and Drug Office, 3rd Floor Federal Building, Main and Water Sts., Telephone WHitehall 2–6494.
PORT ARTHUR, ONT.	– Food and Drug Inspector, Room 313, Public Building, 33 Court St. S., Telephone 4–6521.
REGINA, SASK.	– Food and Drug Inspector, Room 713, Motherwell Building, Telephone LAkeside 3–6836.
SASKATOON, SASK.	– Food and Drug Inspector, Room 307, London Building, Corner of 20th St. East and Third Avenue, P.O. Box 70, Telephone CHerry 4–8662.
BRANDON, MAN.	– Food and Drug Inspector, Room 227, Federal Building, P.O. Box 416, Telephone 9–6577.
VANCOUVER, B.C.	– Superintendent, Inspection Services, Food and Drug Office, Room 504, Federal Building, 325 Granville St., Telephone MUtual 3–7258.
CALGARY, ALTA.	– Food and Drug Inspector, Customs Building, Telephone AMherst 2–1776.
EDMONTON, ALTA.	– Food and Drug Inspector, 541, Federal Building, Telephone GA 4–0251, Local 257.
VICTORIA, B.C.	– Food and Drug Inspector, Room 408, Belmont Building, 805 Government St., Telephone EVergreen 3–5553.
KAMLOOPS, B.C.	– Food and Drug Inspector, Room 7, 345 Victoria St., Telephone 60.

INDEX

– A –

– B –

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